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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,969	04/21/2000	Donald G. Wallace	17067-002040	6560

44444 7590 05/27/2005

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/553,969	WALLACE ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 19-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response dated 2-17-05 is acknowledged.

The following rejection has been maintained:

Claim Rejections - 35 USC § 102

Claims 1, 20-23, 25, 30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,818,517 to Kwee et al (Kwee).

Kwee et al discloses a pharmaceutical preparation comprising a hydrogel polymer and a drug, which is introduced by means of an injection syringe, which reads on the instant applicator having an extrusion orifice. Kwee teaches that the composition provides water necessary for the preparation of the highly viscous hydrogel that is already part of the total composition (col. 1). Thus, the composition of Kwee does not contain any free aqueous phase other than the water that forms a part of the hydrogel. Kwee teaches that the polymer has a swelling capacity but does not state the claimed percentages. However, Kwee teaches dextrin as a suitable polymer (examples), which is a polysaccharide and thus the swelling capacity is inherent to dextrin of Kwee et al. Further, the claimed property of in vivo degradation time being less than one year is inherent to the polymer because Kwee teaches the same class of polymer i.e., a polysaccharide.

Claim Rejections - 35 USC § 103

Claims 19, 24, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee).

Instant claims are directed to protein and non-biological hydrogel and particle size of the hydrogel. While Kwee does not explicitly teach the claimed features, Kwee teaches a hydrogel polymer and suggests polymers such as dextran, starch, polyvinyl alcohol, etc (col. 2) are capable of swelling in water and homogenously injected out of the syringe without causing any practical problems and release the drug slowly over a period of time. Further, Kwee teaches that the polymer is in the form of dry particles (claims) and also suggests that the hydrogel can be used in combination with any drug such as locally active drugs, bactericidal, anti-inflammatories, etc. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use a particulate natural or synthetic (non-biological) polymer such as polyvinyl alcohol, having an appropriate particle size, as a hydrogel in combination with the any desired drug because Kwee suggests that the dry particulate polymer which has a capability to swell is useful in releasing the drug over a long period of time without having the conventional drawbacks such as water being separated from the hydrogel during injection at the site of interest.

Claims 26-29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee) in view of Berg et al.

Kwee fails to teach the claimed protein polymer, a clotting agent such as thrombin, or the claimed combination of polymers.

Berg teaches a collagen wound dressing material comprising resorbable collagen particles of 50 to 350 microns. Berg also teaches addition of several

wound-healing agents such as growth factors, enzyme inhibitors, angiogenesis factors etc (col. 4). Berg teaches that collagen would dressings are capable of swelling at the desired ratios and still be injectable (examples 5 and 10). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ particulate collagen of Berg as a hydrogel in the teachings of Kwee and use the hydrogel alone or in combination with the hydrogels of Kwee for releasing drugs such as wound healing agents because Berg suggests that collagen dressings are capable of being resorbable, allow cellular in growth, and protect the wound to be treated while still permitting the required diffusion of gases and liquids.

Response to Arguments

Applicant's arguments filed 2017-05 have been fully considered but they are not persuasive.

Kwee:

Applicants argue that Kwee fails to teach extrudable hydrogel as claimed because Kwee states hydrogel that contains gee water and is difficult to extrude through a syringe (t col. 1, lines 35-45). To address the problem, Kwee simply proposes adding a thickening agent to improve the syringe ability of the original hydrogel, which still contains free water (Kwee at col. 1, lines 45-48; emphasis added). Absent evidence to the contrary, Applicants argue that Kwee as describing the addition of a water-soluble viscosity-enhancing agent to render the free water in their hydrogel more viscous and that there is nothing to suggest that

the thickening agent somehow provides a hydrogel that is substantially free from a free aqueous phase, as presently claimed.

Applicants' arguments are not persuasive because instant claims are directed to a hydrogel and the claims do not exclude the presence of a thickening agent in the hydrogel. Instant claims do not recite hydrogel as one compound and instead can be interpreted as a composition, thus allowing for the thickener (of Kwee) to be present. Further, it is argued that the second embodiment of Kwee includes two compartments with the first compartment containing dry polymer particles and the second compartment contains water, to create a hydrogel on mixing. Applicants argue that yet there is nothing in Kwee to suggest that the result will be a hydrogel that is substantially free from a free aqueous phase, as presently claimed. Applicants submit that Kwee hydrogel still contains free water, albeit a more viscous free water due to the addition of a water-soluble thickening agent and hence Kwee anticipate instant claims. Applicants arguments are not found persuasive because on one hand applicants argue that a thickening agent is added to the hydrogel (of Kwee) to thicken the composition and reduce water content and on the other hand they argue that even in the presence of thickening agent, the hydrogel still contains free water, without any evidence. Kwee clearly states that the hydrogel composition is ultimately for injecting through a syringe into the body cavity (col. 2, lines 8-14), which implies that the hydrogel is completely extrudable. The fact that Kwee desires absorption of water by swellable polymers is further supported by the teaching of Kwee that moistening agents are added to hydrogel (col. 2, lines 65-68).

Applicants argue that Kwee fails to teach each and every element of the present claims for the reasons mentioned above and that the action has not established the existence of general knowledge available in the art for one to modify the teachings of Kwee. However, applicants' arguments are not persuasive because of the explanation in the previous paragraph. Further, the examiner's position is supported by the teachings of Kwee that the thickening agent is chosen so as to raise the viscosity of the quantity of water needed to prepare the hydrogel, which meets the instant imitation "substantially free of free water". Therefore, one of an ordinary skill in the art would have accordingly modified the teaching of Kwee using the appropriate amount of thickening agent such that the desired viscosity of hydrogel is achieved.

Kwee in view of Berg:

Applicants argue that Kwee fails to teach or suggest each and every element of presently pending independent claims 1 and 34, which recite a hydrogel that is substantially free from a free aqueous phase. It is argued that Berg fails to remedy the deficiencies of Kwee, because Berg fails to teach or disclose a hydrogel that is substantially free from a free aqueous phase as presently claimed. Applicants requested a clarification of the Berg patent cited by examiner. As applicants correctly identified examiner referred to the only one Berg patent cited during the prosecution of the instant application i.e., 4,837,285 Applicants' arguments with respect to the rejection of Kwee in view of Berg have been considered but not found persuasive because as explained in the previous paragraphs, Kwee does teach the claimed hydrogel. The motivation to add the

collagen hydrogels of Berg in the teachings of Kwee comes from the fact that both Kwee and Berg are directed to hydrogel polymers for therapeutic purposes and Berg suggests that collagen hydrogels are capable of swelling, injectable and are resorbable by the body. Therefore, the rejection has been maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 20, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600